

THIRTY-FIFTH MEETING

NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY COUNCIL

January 21, 2000

**National Institutes of Health
Bethesda, Maryland**

MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened for its thirty-fifth meeting on January 21, 2000, in Conference Room 6, Building 31-C, National Institutes of Health (NIH), Bethesda, MD. Dr. James F. Battey, Jr., Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chairperson. In accordance with Public Law 92-463, the meeting was:

Open: January 21, 2000: 8:30 a.m. to 12:30 p.m., for the review and discussion of program development, needs and policy; and

Closed: January 21, 2000: 12:30 p.m. to 2:35 p.m. for review of individual grant applications.

Council members present:¹

Dr. Rita S. Berndt
Dr. Gail D. Burd
Dr. Bernard Cohen
Dr. David P. Corey
Dr. Robert R. Davila
Ms. Rebecca S. Dresser
Dr. Judy R. Dubno

Dr. Jacqueline E. Jones
Dr. Miriam H. Meisler
Dr. Everett R. Rhoades
Ms. Donna L. Sorkin
Dr. Bettie M. Steinberg
Ms. Virginia W. Stern

Council member absent:

Ms. Jane H. Fraser
Dr. Bernard A. Harris
Dr. Ronald R. Hoy

Dr. Orlando L. Taylor
Dr. Gregory T. Wolf

¹For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a real or apparent conflict of interest might occur. This procedure applies only to individual discussion of an application and not to "en bloc" actions.

Ex-Officio Members absent:

Dr. Lucille B. Beck
Dr. John R. Franks
Dr. Michael E. Hoffer

The Council roster is found as Appendix 1.

Various members of the public, as well as NIDCD staff and other NIH staff, were in attendance during the open session of the Council meeting. A complete list of those present for all or part of the meeting is found in Appendix 2.

I. Call To Order and Opening RemarksDr. James F. Battey, Jr.

The meeting was called to order by Dr. Battey, Director, NIDCD, who expressed his appreciation to all Council members for their service and advice to the Institute.

II. Council ProceduresDr. Craig A. Jordan

Procedural Matters

Dr. Jordan discussed important procedural matters, including requirements imposed by the Government in the Sunshine Act and the Federal Advisory Committee Act. The necessity of members avoiding conflict of interest, or the appearance thereof, was stressed, as was the need to maintain confidentiality concerning the proceedings and materials related to the closed portion of the meeting. Dr. Jordan announced that the Council meeting would be open to the public during the morning session, but would be closed for consideration of grant applications during the afternoon.

Consideration of Minutes from the Meeting of October 7, 1999

Dr. Battey called members' attention to the Minutes of the Council's meeting of October 7, 1999. The minutes were approved as written.

Confirmation of Dates for Future Council Meetings

Dates for the Council meetings through September 2002 have been established. A list of these meetings was distributed to the Council members. The next meeting of Council is scheduled for Wednesday, May 24, 2000 and will be held on NIH's Bethesda campus.

III. Report of the Director, NIDCD.....Dr. Battey

Budget Considerations

Using a pie chart, Dr. Battey began his review of the Institute's FY 2000 budget. He indicated that the Research Project Grants category would be \$187 million or 70.6%, of the entire appropriation. Other budget categories include \$11 million (4.2%) for R&D contracts; \$23 million (8.7%) for Intramural Research; \$10 million (3.8%) for Research Management and Support; \$9 million (3.4%) for Research Training; \$5 million (1.9%) for Other Research; and \$20 million (7.5%) for Research Centers.

Dr. Battey next discussed how the nearly \$51.5 million available for competing research project grants will be allocated for FY2000 initiatives and Councils. After consideration of pre-existing commitments, approximately \$14.9 million is available for the January Council. As is traditionally done in the NIDCD, 15 percent of this (\$2.2 million) will be designated for High Program Priority. This leaves approximately \$12.7 million available for the initial pipeline, to the 30th percentile.

Copies of the slides Dr. Battey used for his budget presentation are included in these Minutes as Appendix 3.

IV. Report of the Director, Division of Extramural Research.....Dr. Robert Dobie

New Staff Member

Dr. Dobie introduced Dr. Barry J. Davis, who recently joined the DER as a Health Scientist Administrator. Dr. Davis is managing the taste portfolio in the Voice, Speech, Language, Smell and Taste Branch of the Division of Extramural Research. Dr. Davis came to the NIDCD from the Department of Anatomy & Neurobiology, University of Maryland School of Medicine.

NIDCD Multiple Project Center Grants (P50) Program

Dr. Dobie discussed the NIDCD Multiple Project Center Grants (P50) Program, which was announced in the NIH Guide in July 1999. The NIDCD uses multiple project center grants to support interdependent, interrelated, and multidisciplinary approaches to research in the mission areas of the Institute. Potential applicants for P50 grants are required to consult with NIDCD program staff and provide a written letter of intent before submission of an application. The Institute has received and reviewed a total of four letters of intent for the first application deadline of February 1, 2000.

The last receipt date for new and competing P01s and the old P50s was October 1, 1999. Those applications will be considered at the May 2000 Council meeting, marking the end of the competitive process for the old P01/P50 program for the NIDCD. There are several existing P01s and P50s that will remain active for the number of years for which they were originally approved.

The Communication Disorders Review Committee will be reviewing the new P50 applications beginning at the June 2000 meeting. They will receive an introduction to the new program at their March 2000 meeting by both program and review staff. The new P50 program is requiring significant changes for both the applicant community and the NIDCD program/review administrators.

Update on the P30 Research Core Centers Program

Ten letters of intent for the Research Core Center Program (P30) were received for the November deadline. Applications were due January 19, 2000. The Scientific Review Branch, DER, will be reviewing these applications in a Special Emphasis Panel, and the applications will be brought before the Council at the September 2000 meeting.

Impact of Budget Increases on New/Competing Grant Funding

Dr. Dobie introduced the issue of recent large budget increases and how they have resulted in large increases in new/competing grant funding, with similarly increasing out-year commitments. He discussed the possibility of experiencing reductions in the number of new/competing grants that can be funded if we are granted smaller budget increases in future years. Council discussed the current issue and the potential future impact.

Discussion of Proposed Contract Initiative

The current process for the issuance of NIDCD Requests for Applications (RFAs) and Requests for Proposals (RFPs) involves Council during the concept clearance phase. Dr. Dobie called Council's attention to a summary of the concept now being proposed for implementation, titled "The Feasibility of an Intraneural Auditory Prosthesis Stimulating Electrode Array." The NIDCD has, for many years, supported a contract program on auditory prostheses in conjunction with the NINDS Neural Prosthesis Program. Dr. Dobie introduced Dr. William Heetderks, who is the Project Officer for these contracts.

Dr. Heetderks presented the concept for this new RFP on auditory prostheses. The initiative evolved from discussions at the 1999 Asilomar Conference on Implantable Auditory Prostheses. The concept is to design and develop an intraneural electrode array capable of providing tonotopic representation similar to an auditory prosthesis, and testing its safety and efficacy in an animal model of the human auditory nerve.

Council concurred with the concept initiative as described by Dr. Heetderks.

V. Council Operating Procedures.....Dr. Jordan

Dr. Jordan called Council's attention to a revised copy of the *Council Operating Procedures* which had been provided to each member prior to the meeting. The *Council Operating Procedures* state those actions which Council empowers staff to take without specific prior Council approval. He opened discussion of this document by

explaining that it is the Institute's procedure to review the *Council Operating Procedures* annually at the January Council. Dr. Jordan explained several recommendations made by staff for modifying the current version of the procedures. The revised document was endorsed unanimously for the current year, and is included in these minutes as Appendix 4.

Dr. Jordan directed Council to the Interim Actions Report contained in their workbook. This report informs the Council of grant award actions performed by staff, on behalf of the Council, since the last meeting.

VI. Bioengineering Activities at the NIH..... Dr. Wendy Baldwin

Dr. Battey introduced Dr. Wendy Baldwin, NIH's Deputy Director for Extramural Research. Dr. Baldwin had agreed to apprise the Council on current bioengineering activities at the NIH.

She informed the Council that in recognition of the potential benefits to human health that could be realized from applying and advancing the field of bioengineering, the NIH Director formally established the Bioengineering Consortium (BECON) in February 1997. BECON is the focus of bioengineering issues at the NIH and is composed of senior-level representatives from each of the NIH centers, institutes, and divisions. The Consortium also includes representatives of other federal agencies concerned with biomedical research and development.

The mission of the Consortium is to foster new basic understandings, collaborations, and transdisciplinary initiatives among the biological, medical, physical, engineering, and computational sciences. In support of this objective, BECON coordinates and facilitates research grants, training opportunities, and scientific symposia associated with biomedical engineering. Regular monthly meetings of the Consortium are conducted to discuss program status, future needs and directions, and topics of interest to the biomedical engineering community.

Dr. Baldwin outlined several ongoing and past BECON initiatives, including program announcements for grants, annual symposia, and the pending formation of an Office on Bioengineering and Bioimaging within the Office of the Director, NIH.

VII. Report of the Work Group on Research Training and Career Development (WGRTCD)..... Dr. Allen Ryan

The Work Group on Research Training and Career Development (WGRTCD) met in Bethesda, MD on December 8 and 9, 1999, to discuss research training and career development relevant to the mission areas of the National Institute on Deafness and Other Communication Disorders (NIDCD). The Report of the Work Group was posted on the Council Homepage for review, and Dr. Allen Ryan, who chaired the Work Group, discussed the Work Group's Report.

The WGRTCD was provided with information on research trainees supported in the past by the NIDCD, and on NIH-trained individuals who had made the transition from training to independent support. Additional information was gathered from individuals who had made this transition without NIH training support.

The WGRTCD agreed that goals of the NIDCD should include enhanced efforts to recruit promising students into research areas relevant to the Institute. In addition, the NIDCD should provide the highest possible quality of research training within its mission areas, and should encourage the research training of health professionals working within its mission areas. Finally, the Institute should encourage the transition of trainees to independent investigator status, and enhance the prospects of its trainees to obtain research positions of the highest quality.

To accomplish these goals, the WGRTCD developed recommendations which were presented and discussed by Dr. Ryan. Council unanimously endorsed the recommendations from the WGRTCD.

[Executive Secretary's Note: The WGRTCD recommendations were made available to the scientific community for comment following the meeting. The recommendations and background information can be found at:
<http://www.nih.gov/nidcd/funding/policy/wgrtcdnotice.htm>.]

VIII. Report of the Acting Director, NIH Dr. Ruth Kirschstein

Dr. Battey introduced Dr. Ruth F. Kirschstein, who was recently appointed Acting Director, NIH. Dr. Kirschstein gave a brief overview of her past service at the NIH, including many years in directing the National Institute on General Medical Sciences.

Next, she discussed NIH's plans and preparations for the upcoming budget hearings. She explained that Congressional support of biomedical research has greatly increased, and stated that it is incumbent on the NIH to stress the importance and relevance of research, and how our funds are being spent. She discussed several areas in which Congress has expressed heightened interest, including the fields of biotechnology and imaging technology.

NIH is also looking to reduce and/or eliminate health disparities around the country, particularly among minorities. Institute Directors are being asked to serve on a Work Group to help develop a Strategic Plan for Research in Health Disparities before the middle of March 2000. In this case, research in health disparities is being defined as research directed at determining the basis for, or means for reducing disparities in the burden of disease experienced by different racial groups. Dr. Kirschstein requested

that Dr. Battey involve the Council in this initiative, which has been designated one of the highest priorities for the Secretary, DHHS.

Before closing, Dr. Kirschstein discussed current activities surrounding women's health initiatives, and then entertained comments and questions.

CLOSED SESSION

IX. Council Consideration of Pending Applications

The Council gave special attention to applications from foreign institutions and to applications involving issues related to protection of human subjects, animal welfare, biohazards and/or minority and gender representation in study populations as identified by the initial review groups.

A. Research Project Grant Awards

1. Consideration of Applications: On the Council's agenda was a total of 130 research grant applications; 101 applications had primary assignment to NIDCD, in the amount of \$22.05 million first-year direct costs. It is anticipated that, of the applications competing at this Council, NIDCD will be able to pay first-year direct costs through the 30th percentile.

B. Special Programs Actions

1. Small Business Innovation Research Awards (SBIR). The Council recommended support for six Phase I (R43) and one Phase II (R44) application.
2. Small Business Technology Transfer (STTR): The Council recommended support for two Phase I applications.
3. Small Grants (R03): The Council recommended support for eleven applications.
4. Clinical Research Centers (P50): The Council recommended support for one application.
5. Conference Grants (R13): The Council recommended support for four applications.

6. Academic Research Enhancement Awards (R15): The Council recommended support for three applications.
7. Exploratory Developmental Grants (R21): The Council recommended support for eight applications.

C. Training Programs

1. Institutional National Research Service Awards (T32): The Council recommended support for seven applications.

D. Career Development Programs

1. Mentored Clinical Scientist Development Award (K08): The Council recommended support for one application.

X. Adjournment: The meeting was adjourned at 2:35 p.m. on January 21, 2000.

XI. Certification of Minutes

We certify that, to the best of our knowledge, the foregoing minutes and attachments are accurate and correct.¹

Craig A. Jordan, Ph.D.
Executive Secretary
National Deafness and Other Communication
Disorders Advisory Council

James F. Battey, Jr., M.D., Ph.D.
Chairman
National Deafness and Other Communication
Disorders Advisory Council

Director
National Institute on Deafness and
Other Communication Disorders²

Jeannie Combs
Council Assistant

¹These minutes will be formally considered by the Council at its next meeting; corrections or notations will be incorporated in the minutes of that meeting.

APPENDICES

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Appendix 1

Roster

National Deafness and Other Communication Disorders Advisory Council

Chairperson

Battey, James F., Jr., M.D., Ph.D.

Director

National Deafness and Other Communication Disorders

Bethesda, Maryland 20892

BERNDT, Rita S., Ph.D.

2002

Professor

Department of Neurology

University of Maryland

School of Medicine

22 South Greene Street

Baltimore, Maryland 21201

BURD, Gail D., Ph.D.

2003

Associate Professor

Department of Molecular and Cellular

Biology

Life Sciences South Building 444

University of Arizona

Tucson, Arizona 85721

COHEN, Bernard, M.D.

2002

Morris B. Bender Professor

Department of Neurology

Mount Sinai School of Medicine

City University of New York

1 East 100th Street

New York, New York 10029

COREY, David P., Ph.D.

2001

Professor of Neurobiology

Harvard Medical School

Neurobiologist, Department of Neurobiology

Massachusetts General Hospital

Boston, Massachusetts 02114

DAVILA, Robert R., Ph.D.

2000

Vice President

National Technical Institute for the Deaf

Rochester Institute of Technology

Lyndon B. Johnson Building, Room 2130

52 Lomb Memorial Drive

Rochester, New York 14623-5604

DUBNO, Judy R., Ph.D.

2003

Professor

Department of Otolaryngology-

Head and Neck Surgery

Medical University of South Carolina

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Walton Research Building Room 608

Charleston, SC 29425

DRESSER, Rebecca S., J.D.

2001

Professor, School of Law

and Program for the Humanities in Medicine

Washington University School of Law

1 Brookings Drive

Campus Box 1120

St. Louis, Missouri 63130

FRASER, Jane H.

2000

President

Stuttering Foundation of America

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Memphis, Tennessee 38111

HARRIS, Bernard A., Jr., M.D. 2002
Vice President
Microgravity and Life Science
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HOY, Ronald R., Ph.D. 2003
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JONES, Jacqueline E., M.D. 2002
Associate Professor of
Clinical Otolaryngology
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MEISLER, Miriam H., Ph.D. 2003
Professor
Human Genetics Department
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University of Michigan
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RHOADES, Everett R, M.D. 2000
Associate Dean for Community Affairs
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SORKIN, Donna L. 2002
Alexander Graham Bell Association
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3417 Volta Place NW
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STEINBERG, Bettie M., Ph.D. 2000
Chief, Otolaryngology Research
Department of Otolaryngology
Long Island Jewish Medical Center
270-05 76th Avenue
New Hyde Park, New York 11040

STERN, Virginia W. 2001
American Association for the
Advancement of Science
1200 New York Avenue, N.W.
Washington, D.C. 20005

TAYLOR, Orlando L., Ph.D. 2001
Dean
Graduate School of Arts and Sciences
Howard University
Washington, D.C. 20059

WOLF, Gregory T., M.D. 2001
Chair, Department of Otolaryngology-
Head and Neck Surgery
University of Michigan Medical Center
1500 East Medical Center, Box 0312
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Ex-Officio Members:

BECK, Lucille B., Ph.D.
Director
Audiology and Speech
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FRANKS, John R., Ph.D.
Chief, Bioacoustics and
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Washington, D.C. 20201

KIRSCHSTEIN, Ruth F., M.D.
Acting Director
National Institutes of Health
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EXECUTIVE SECRETARY

JORDAN, Craig A., Ph.D.
Chief, Scientific Review Branch
Division of Extramural Research, NIDCD
6120 Executive Boulevard, Suite 400C
Bethesda, Maryland 20892-7180

Appendix 2

NIDCD Director's Report Slides

As Presented By
James F. Battey, Jr., M.D., Ph.D.
NIDCD Advisory Council Meeting

January 21, 1999

**National Institute on Deafness and Other Communication Disorders
Budget Mechanism**

(Dollars in thousands)

	<u>FY 2000 Appropriation</u>	<u>Percent of Total</u>
Research Projects Grants	\$186,611	71%
Research Centers	19,682	7%
Other Research	5,603	2%
Total, Res. Grants	211,896	80%
Individual Training	2,716	
Institutional Training	5,971	
Total, Training	8,687	3%
R&D Contracts	11,478	4%
Intramural Research	23,069	9%
Research Mgmt. & Support	10,055	4%
TOTAL	265,185	

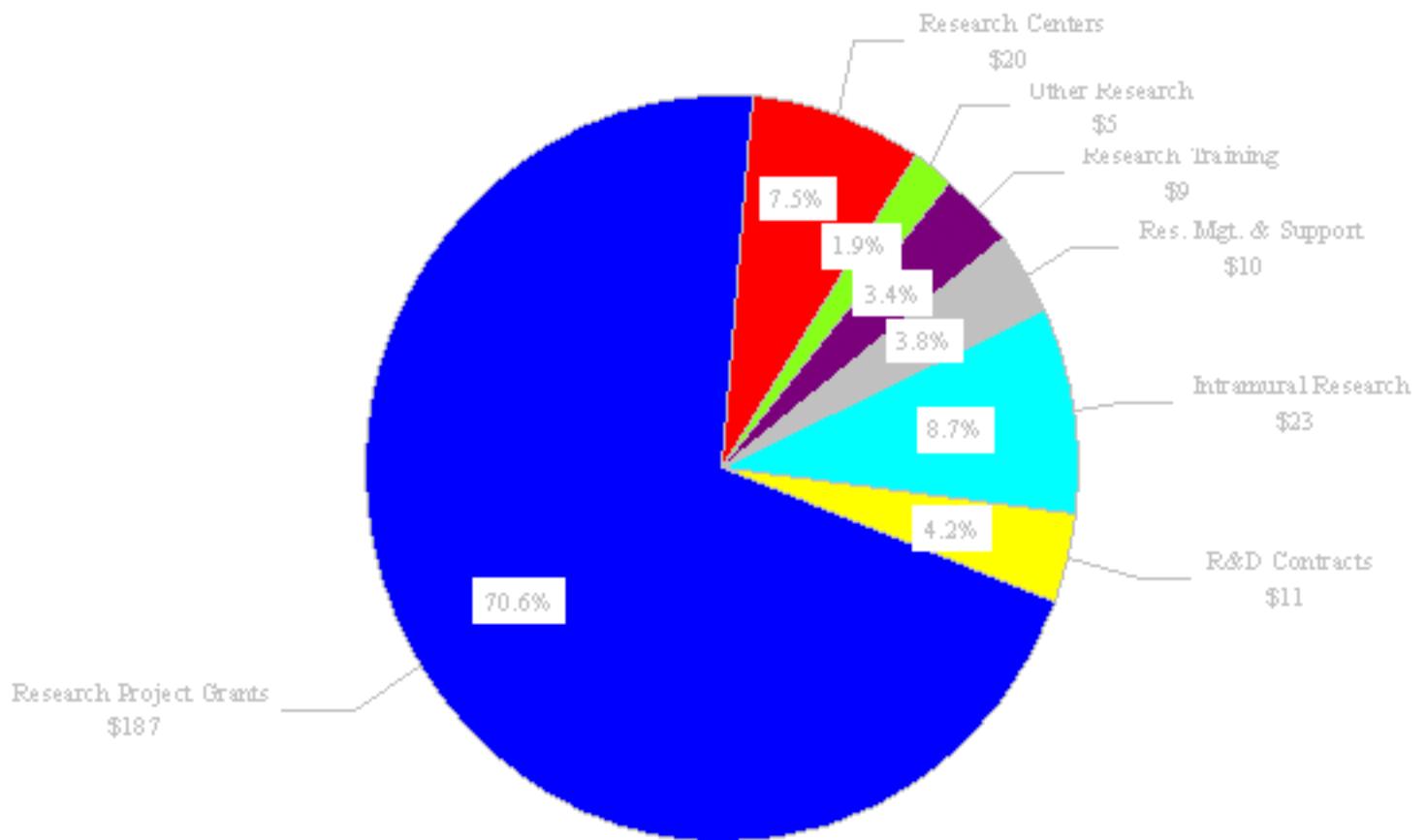
National Institute on Deafness and Other Communication Disorders
Research Project Grants
(Dollars in thousands)

FY 2000
Appropriation

	No.	Amount
Noncompeting	525	\$128,321
Admin. Supp.	(25)	900
Competing	194	51,460
Subtotal, RPGs	719	180,681
SBIR/STTR	28	5,930
Total, RPGs	747	186,611

FY 2000 Appropriation

(Dollars in Millions)



Appendix 2

ATTENDANCE LIST

Other than Council members, attendees at the January 2000 Council meeting included:

NIDCD Staff:

Office of the Director

Luecke, Donald H., M.D., Deputy Director

Phillips, Isabelle, Secretary

Lopez, Joyce, Program Specialist

Office of Administration

Kerr, W. David, Executive Officer

Financial Management Branch

Sparks, Patience, Budget Officer

Information Systems Management Branch

Grimes, Brenda, Computer Specialist

Science Policy and Legislation Branch

Smith, Mary Acting Chief

Wong, Baldwin Program Analyst

Division of Extramural Research

Dobie, Robert A., M.D., Director

Combs, Jeannie, Program Analyst

DaSilva, Maria, Program Assistant

Clinical Trials Branch

Gulya, A. Julianna, M.D., Chief

Grants Management Branch

Hunt, Sharon, Chief

Dabney, Sherry, Grants Management Officer

McNamara, Castilla, Grants Management Specialist

Hearing and Balance/Vestibular Sciences Branch

Donahue, Amy M., Ph.D., Chief

Freeman, Nancy, Ph.D., Health Scientist Administrator

Johnson, Thomas, Ph.D., Health Scientist Administrator

Luethke, Lynn, Ph.D., Health Scientist Administrator

Sklare, Daniel A., Ph.D., Health Scientist Administrator

Scientific Review Branch

Jordan, Craig A., Ph.D., Chief

Burrous, LaTasha,

Oaks, Stanley C., Ph.D., Scientific Review Administrator

Stick, Melissa J., Ph.D., M.P.H., Scientific Review Administrator

Voice, Speech, Language, Smell, and Taste Branch

Cooper, Judith A., Ph.D., Chief

Ansel, Beth M., Ph.D., Health Scientist Administrator

DeWalt, Linora, Secretary

Small, Rochelle, Ph.D., Health Scientist Administrator

Davis, Barry, Ph.D., Health Scientist Administrator

Center for Scientific Review, NIH

Martin, Michael, Ph.D., Division Director

Kimm, Joseph, Ph.D., Scientific Review Administrator

Kenshalo, Daniel, Ph.D., Scientific Review Administrator

Meadow-Orlans, Kathryn, Ph.D., Scientific Review Administrator

Sostek-Miller, Anita, Ph.D., Scientific Review Administrator

Others

Moss, Sharon, Ph.D., American Speech and Hearing Association

Ryan, Allen, Ph.D., University of California, San Diego

Baldwin, Wendy, Ph.D., Deputy Director for Extramural Research, NIH

Swaja, Dick, Office of Extramural Research, NIH

NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS

ADVISORY COUNCIL

OPERATING PROCEDURES

(As endorsed by Council January 21, 2000)

The Institute staff may take the following actions without Council review. All actions shall be documented and presented to the Council for its information at the first appropriate opportunity.

1. Approval of New Principal Investigator or Program Director

Give approval of a new principal investigator or program director to continue an active grant at the grantee institution.

2. Replacement of Research Grant for Investigator Who Moves to a New Institution

Make research grant awards equal to the remaining committed support for continuing work under the same principal investigator when that principal investigator moves from one institution to another. This provision will not be automatic, however. Staff may approve less than the remaining committed support and will in all cases carefully document for the file the rationale for the action.

3. Awards for Orderly Termination

Make appropriate awards for orderly termination of competing continuation applications which were not recommended for further consideration, or which received a score too low for payment; this procedure is to be used in those cases where sudden termination of the grant would cause a serious loss of scientific material or impose a hardship to already employed personnel. In such cases, (1) the grant usually should be for a period not to exceed twelve months, (2) careful review should be given to needs for salaries and consumable supplies, (3) usually no funds would be provided for additional equipment or travel, and (4) in the case of training grants, support would be provided for those trainees already in the program.

4. Awards for Interim Period Due to a Deferral

Make awards in an appropriate amount and for an appropriate interim period of time when a recommendation of deferral on a competing continuation application results in a loss of continuity of the active research or training program. Careful review should be

given to the needs for personnel and consumable supplies; however, usually no funds would be provided for equipment or travel.

5. Supplemental Support to Existing Research and Training Awards

Provide additional support up to \$100,000 in direct costs per year to carry out the scientific, administrative and fiscal intent of the research or training award. The additional support may be necessary to: a) make NIH-wide supplemental awards for under-represented minorities, individuals reentering science, or individuals with disabilities; b) provide administrative increases; c) cover unanticipated costs; or d) ensure effective operation of the recommended program. Increases greater than \$100,000 will be presented to the NIDCD Advisory Council for approval before an award is made.

Institute staff may take the following actions without subsequent reporting to the Council.

1. Continuation of Grant in Temporary Absence of Principal Investigator or Program Director.

Give approval for continuation of grants in the temporary absence of the principal investigator or program director.

2. Extension of Project Period Dates

Take necessary action on extensions of project period end dates without additional funds.

3. Scientific Evaluation Grants

Take final action in awarding supplements to the chairpersons of the NIDCD research and training review committees in an amount necessary to carry out the functions of the committees.

